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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,282	12/19/2001	Mark W. Bleyer	3433-333	5918

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EXAMINER

LEAVITT, MARIA GOMEZ

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

07/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/025,282

Applicant(s)

BLEYER ET AL.

Examiner

MARIA LEAVITT

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-60 and 62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-60 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Detailed Action

After a telephonic interview with Applicants' attorney of record, Kenneth A. Gandy, on February 01, 2008, it was agreed that claims 54-60 and 62 were enabling with regard to the bonding techniques, such that those skilled in the art would understand from the specification of the present application that the applicants had possession of the claimed invention, and would be fully enabled to practice the claimed scope of the invention without undue experimentation. A summary of the interview was filed on February 13, 2008. Accordingly, rejection of claims 54-60 and 62 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and rejection of claims 54-60 and 62 under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement, have been withdrawn.

However, upon further consideration the final office action mailed on 12-10-2007 is vacated in favor of a new non-final office action in view of reconsideration of search of relevant prior art for claims 54-60 and 62.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Status of claims. Claims 54-60 and 62 are currently pending and claims 36-53 and 62-65 have been canceled by Applicants' amendment filed on 06-10-2008
3. Therefore, claims 54-60 and 62 are currently under examination to which the following grounds of rejection are applicable.

Withdrawn rejections in response to Applicant arguments or amendments

Claim Rejections - 35 USC § 103

In view of Applicants' cancellation of claims 36-53 and 62-65, rejection of claims 36-45, 53 under 35 USC § 103 as being unpatentable over Voytik-Harbin et al., et al., et al., (US Patent No. 6,444,229) in view of Stinson et al., (US 2004/0111149 A1), is rendered moot.

In view of Applicants' cancellation of claims 36-53 and 62-65, rejection of claims 45-53 and 63-65 under 35 USC § 103 as being unpatentable over any of Kropp (Urology, 1995), Whitson (US patent No. 5,997,575) and Bonadio (US patent No. 5,942,496) each of them taken with Stinson et al., (US 2004/0111149 A1), is rendered moot.

In view of Applicants' cancellation of claims 36-53 and 62-65, rejection of claims 45-53 and 63-65 under 35 USC § 103 as being unpatentable over any of Badylak et al., (WO 96/24661), Badylak 2 (WO 96/25179), Cook et al., (WO 98/22158), Fearnot (US 6,358,284), Badylak 3 (US 2004/0078076) each of them taken with Stinson et al., (US 2004/0111149 A1), is rendered moot.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

Claims 54-60 and 62 are newly rejected under 35 USC § 103 as being unpatentable over Badylak et al., (US Patent No. 6,099,567, effective priority filing date, 10 December 1996) in view of Stinson et al., (US 2004/0111149 A1).

Badylak et al., discloses compositions comprising the tunica submucosa of the intestine of warm-blooded vertebrates that can be used as a matrix for the regrowth of tissues replaced by the graft to promote or induce such regrowth of endogenous tissue (col. 1, lines 21-32). Moreover, Badylak et al., teaches that the stomach submucosa compositions can be administered to the host

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in either solid or sheet form by surgical implantation alone or in combination with other art-recognized implant compositions (col. 3, lines 65-67). Furthermore, Badylak et al., discloses that the stomach submucosa composition can be folded or partially everted to provide multiple layers for gripping, for example, with spiked washers or staples (col. 5, lines 50-55) or “multiple strips/pieces of stomach submucosa can be overlapped and compressed, under conditions allowing dehydration of the tissue, to fuse the strips/pieces of the stomach submucosal tissue into a unitary multi-laminate construct (col. 6, lines 4-7). **Current claims 54-55 and 62.** In addition, Badylak et al., teaches that the submucosa composition is typically prepared from stomach tissue harvested from animals raised for meat production, including pigs (col. 2, lines 60-64) **Current claims 56, 59 and 60.**

Badylak et al., does not specifically teach that a radiopaque marker such as tantalum, bismuth and barium are disposed between the strips of the collagenous material.

However, at the time the invention was made, Stinson teaches that there is a need for bioabsorbable radiopaque markers for use on an implantable biomaterial such as an endoprosthesis, e.g., stents and grafts, in order to improve radiopacity and visualize the passage and placement of the endoprosthesis, particularly by using radiopaque endoprosthesis (p. 1, paragraphs [0002]-[0004]). Moreover, Stinson et al., discloses that bioabsorbable-radiopaque markers may have one or more hollow, cavity, or porous portions wherein radiopaque material may be disposed (p. 2, paragraph [0021]). In addition, Stinson discloses that marker is adapted to be disposed on or adjacent the endoprosthesis and includes a proximal end, distal end, thickness, bioabsorbable material, and a radiopaque material wherein the radiopaque material may be a liquid, solid, powder, gel, particle, or combinations thereof (p. 4, paragraph [0031]).

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Furthermore, the preferred metallic elements for biocompatibility and radiopacity as taught by Stinson include tantalum, bismuth and barium (p. 3, paragraph [0027]. **Current claims 57 and 58.**

Therefore, in view of the benefits of using bioabsorbable radiopaque markers in grafts to enhance radiopacity and visualize the placement of the implantable graft, as taught by Stinson, it would have been *prima facie* obvious for one of ordinary skill in the art to incorporate a radiopaque marker in the implantable multilaminar device as taught by Badylak. The use of bioabsorbable collagenous materials as well as radiopaque elements was routine or well-established in the art at the time of filing. The disclosure of the specification as-filed fails to provide any new elements in the product as claimed. Therefore, the skilled artisan would have had a reasonable expectation of success in generating a radiopaque implantable device because Badylak teaches implantable biomaterial devices for remodeling tissue in multiple layers, for example, and Stinson et al., discloses bioabsorbable-radiopaque markers used as liquid, solid, powder, gel and particles to use in implantable grafts to enhance visualization.

Conclusion

Claims 54-60 and 62 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Weitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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